Practical Strategies and Advice for Managing Ethical Concerns in End-of-Life Research

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Abstract

Problem/Issue Statement

A growing national interest in improving end-of-life care has increased the amount of research involving dying patients and their families. However, questions about how to best balance the pressing need for research with protecting participants trouble both investigators and institutional review boards (IRBs). Furthermore, ethical concerns were identified as a potential barrier to advancing end-of-life science at the 2004 NIH State of the Science Consensus Conference. This NIH-funded study describes ethical concerns and practical strategies for managing ethical challenges in the conduct of end-of-life research.

Description of Research

Methods: A qualitative, exploratory case study design followed the development of end-of-life research from proposal generation through the review process. Inclusion criteria mirrored those used in the NIH State of the Science Report. Cases were identified through a search of active studies in the NIH RePORT database and an internet search of active research funded by private foundations and institutions. Data were collected from a purposive sample of 34 principal investigators who participated by phone in semi-structured interviews and provided document data regarding their experiences with the grant and IRB review processes. Interviews were recorded and transcribed with identifying information removed to protect confidentiality. Relevant document data were extracted and de-identified. Data were analyzed using exploratory qualitative case study methods.

Results: The most common ethical concerns about research with end-of-life populations were recruitment strategies, the burden of study procedures, and population vulnerability. Strategies to address these concerns included gathering data about the benefits of research participation, consulting with the IRB and with more experienced researchers, using non-threatening language in the consent and other materials, being flexible in data collection protocols to accommodate participant limitations, creating back-up plans in the event of crisis, partnering with clinicians to ensure prompt attention to symptom reports, and addressing the training and emotional needs of research staff . PIs advise IRBs to seek out expert consultants for end-of-life studies, work collaboratively with investigators, simplify the

consent process, and be open to the benefits of research participation for dying patients and their families rather than assuming harm will occur.

Conclusion: Investigators use a variety of strategies to manage ethical issues in the conduct of end-of-life research. They advise IRBs to seek out expertise, enhance knowledge of the population, and work collaboratively with investigators. Future research will focus on gathering systematic data regarding the experiences of dying patients and their families with end-of-life research.